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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,719	01/13/2004	Mark E. Cook	960296.00108	2648

27114 7590 07/18/2006

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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,719	COOK ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of remarks filed on 4/20/2006. Applicant's arguments have been fully considered but are not persuasive for the reasons of record and those stated below. This action is final.

Claims 1-16 are pending.

Withdrawn rejections:

Applicant's arguments, see remarks, filed 04/20/2006, with respect to claims 1-5 and 7-10 rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 5,603,959) have been fully considered and are persuasive. The Examiner agrees that linoleic as disclosed by Horrobin et al. is not structurally the same as conjugated linoleic acid of the instant invention. The rejection of claims 1-5 and 7-10 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-12 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 6,245,811).

Horrobin et al. disclose a method for treating a disorder (rheumatoid arthritis) comprising administering to a patient in need thereof an effective amount of the

compound according to claim 1 where R_1 is an acyl moiety corresponding to an acid (conjugated linoleic acid) (Column 14 lines 55-62; column 15, line 1 and claims 1, 10 and 28). The Examiner interprets the compound to be an ester of conjugated linoleic acid and thus anticipate instant claim 1-5. Doses may be administered to the patient in need thereof orally, enterally, topically, parenterally, (subcutaneously, intramuscularly, intravenously), rectally, vaginally or by any other appropriate route (Column 17, lines 32-36 and claim 28). By patient, the Examiner interprets this to be a human and thus anticipate instant claims 7-12.

Response to arguments:

Applicant amended claim1 to recite "a composition that consists essentially of a conjugated linoleic acid" and asserted that Horrobin et al. do not specifically disclose that conjugated linoleic acid can be used to treat rheumatoid arthritis. The Examiner respectfully disagrees with this opinion. The MPEP states: For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." (See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.) And: If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. (In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)).

Applicant asserted that Horrobin et al. disclose the treatment of rheumatoid arthritis in connection with the use of one or more of GLA, DGLA, SA and EPA but not cLA. The Examiner respectfully disagrees. Horrobin et al. disclose in claim 28 a method of treating a disorder selected from the group consisting of...rheumatoid arthritis...comprising administering to a patient in need thereof an effective amount of the compound of claim 10. Horrobin et al. disclose in claim 10 a compound according to claim 1 where R1 is an acyl moiety corresponding to...conjugated linoleic acid. Therefore, it is the Examiner's position that Horrobin et al. disclose a method of treating rheumatoid arthritis with a compound containing conjugated linoleic acid.

Claim Rejections - 35 USC § 102

Claims 1-13 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Menard et al. (WO 02/09725).

Menard et al. disclose a method for treating degenerative joint disease comprising the step of administering a therapeutically effective amount of a composition comprising linoleic acid, glucosamine and ascorbic acid (claim 1). Isomers of linoleic acid are disclosed (claim 5). Menard et al. disclose that to treat rheumatoid arthritis, a daily administration of formulation will be given in an amount to provide 20 mg/kg/day conjugated linoleic acid to 100 mg/kg/day conjugated linoleic acid (Page 8 line 28-page 9 line 2). The dose is administered by way of tablet/pill thus anticipating an oral administration route (Page 8, lines 8-11 and claim 8). Menard et al. disclose the CLA can be readily incorporated in a dose-dependent manner into the tissues of animals consuming diets containing CLA thus anticipating instant claim 13 (Page 6, lines19-22).

Menard et al. disclose rheumatoid arthritis as a factor affecting human articular cartilage (Page 6, lines 23-30). The Examiner interprets this to mean that the method of treating rheumatoid arthritis is meant for human articular cartilage and thus reads upon instant claims 7-10.

Response to arguments:

Applicant amended claim1 to recite "a composition that consists essentially of a conjugated linoleic acid" and asserted that Menard et al. do not specifically disclose that conjugated linoleic acid alone can be used to treat rheumatoid arthritis. The Examiner respectfully disagrees with this opinion. The MPEP states: For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. And: If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,077,868) in view of Watkins et al. (Journal of the American College of Nutrition 2000, 19(4), 478S-486S).

Cook et al. teach a method for reducing cyclooxygenase 2 mediated inflammation in an animal comprising the step of delivering into the animal an amount of a conjugated linoleic acid effective to reduce the inflammation (claim 7); a method for selectively inhibiting cyclooxygenase 2 activity in an animal having cyclooxygenase 2 acitivity comprising the step of administering to the animal an amount of a conjugated linoleic acid effective to reduce the activity of cyclooxygenase 2 (claim 1); the method wherein the administration step comprises a method selected from the group consisting of oral delivery, intramuscular injection, intravenous injection, transdermal delivery and transmucosal delivery (claim 2); the method wherein the animal is a human (claim 4); the method wherein the conjugated linoleic acid is selected from the group consisting of an 18:2(9c,11t) isomer, an 18:2(9t,11c) isomer, an 18:2(10c,12t) isomer, an 18:2(10t,12c) isomer, a bioactive ester thereof, a salt thereof, and a mixture thereof (claim 5); and a method wherein the CLA is delivered in a dosage of between 1 mg/kg and 1000 mg/kg body weight of the animal (claim 6). An appropriate amount of CLA in the diet is in the range of 0.1% to 5% by weight preferably 0.2% to 0.5% by weight in the diet (Column 3, lines 21-27).

Cook et al. do not expressly disclose a method of treating diseases (rheumatoid arthritis) or conditions caused by type III hypersensitive reactions in a human or non-human animal, the method comprising the step of administering to the animal a composition consisting essentially of a conjugated linoleic acid (CLA) in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal.

Watkins et al. teach that anti-inflammatory diets are associated with decreased pathogenesis of rheumatoid arthritis, reduced inflammatory diseases and lowered cancer risk (Page 483S, Summary). Watkins et al. assert that multiple lines of evidence indicate that up-regulation of COX-2 contributes to inflammation (Page 483S, Summary). Watkins et al. state that the beneficial anti-cancer effect of CLA is likely linked to down-regulation of COX-2 activity (Page 484S, left column last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer CLA, a down regulator of COX-2, to an animal for the purpose of treating rheumatoid arthritis to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Watkins et al. suggest that research would lead to control of inflammatory bone joint disease (rheumatoid arthritis). In addition, the practice of the invention of US 6,077,868 would intrinsically treat rheumatoid arthritis.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie

obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to arguments:

Applicant asserted that Cook et al. do not expressly disclose that CLA can be used to treat a disease or condition caused by type III hypersensitivity and that Watkins et al. do not make up for this deficiency in Cook et al. Applicant asserted that "without the cause-effect relationship established, the use of CLA as a COX-2 inhibitor for the treatment of rheumatoid arthritis would be at most something to try but there would not be any reasonable likelihood of success."

The Examiner respectfully disagrees for the following reasons. It is known in the art that COX-2 catalyzes the synthesis of prostaglandins that cause inflammation and pain (Cook et al., column 1, lines 28-29). Cooke et al. teach that it is important that CLA inhibits COX-2 activity to an extent sufficient to reduce inflammation (Column 2, lines 52-54 and column 5, lines 5-8). Watkins et al. provide the nexus teaching that diets including nutraceutical applications of CLA may be beneficial in moderating COX-2 activity (as demonstrated by Cooke et al.) and might help reduce rheumatoid arthritis (Abstract). Watkins et al. teach that the common link between rheumatoid arthritis, inflammatory diseases and cancer resides in the regulation/expression of COX-2 (Page 483S, summary). Thus, it would have been obvious to one of ordinary skill in the art to administer a compound/composition that modulates COX-2 activity for the treatment of rheumatoid arthritis. One of ordinary skill in the art would have had a reasonable

expectation of success because Watkins et al. teach; "Anti-inflammatory diets, including nutraceutical n-3 fatty acids, are associated with decreased pathogenesis of rheumatoid arthritis" and provides 3 references (Page 483S, Summary).

With respect to the invention of Cook et al. (US 6,077,868) intrinsically treating rheumatoid arthritis, the Examiner was directing Applicant to the fact that the method of Cooke et al. *intrinsically* treats rheumatoid arthritis because Cooke et al. teach the administration of the same compound, conjugated linoleic acid, in the same amount as instantly claimed. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In the absence of any criticality/unexpected results, the presently claimed invention is considered prima facie obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

A prior art disclosure is not limited to its working examples or to its preferred embodiments. (Merck & Co. Inc. v. Biocraft Labs. Inc., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989); *In re Fracalossi* 681 F.2d 792, 794 n. 1, 215 USPQ 569, 570 n.1 (CCPA 1982); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); *In re Boe*, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1996).

Accordingly, the burden of proof is upon Applicants to show that the instantly claimed subject matter is different and unobvious over those taught by the prior art. (See: *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
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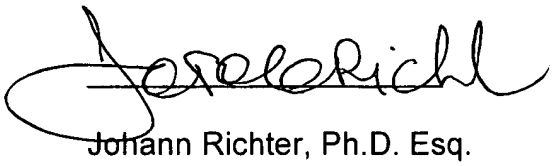

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